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F.D.A. to Weigh At-Home Testing for AIDS Virus

By [GARDINER HARRIS](#)

Federal drug regulators have agreed to consider allowing a [Pennsylvania](#) company to sell the first rapid, at-home [AIDS](#) test that would make testing for the [virus](#) about as easy and accessible as a [pregnancy](#) screen. The move could put to rest 18 years of controversy.

Officials at the Food and Drug Administration and AIDS advocates long worried that people who got an AIDS diagnosis would panic and even consider [suicide](#). So for years, the federal drug officials have insisted that counseling and professional support accompany AIDS tests. This requirement has complicated proposals for at-home tests.

But improved medicines now mean that AIDS is a chronic disease that can often be managed for years, so the fear that a diagnosis might lead to thoughts of suicide have subsided. Just as important, 40,000 people each year continue to be infected by HIV, the virus that causes AIDS. This rate has remained stubbornly high for years. Having tried many other strategies, federal health officials are now increasingly open to the idea that an at-home AIDS test could finally lead thousands to change their behaviors and stop infecting others.

"If we're going to win the war against AIDS, we need to make HIV testing as easy as pregnancy testing," said Dr. Freya Spielberg, a researcher in the Center for AIDS Research at the University of Washington.

A federal advisory board will discuss the proposal for an at-home AIDS test on Nov. 3. After that, the test's maker, OraSure Technologies, based in Bethlehem, Pa., said that it would likely apply formally to sell the device over-the-counter.

The test, called OraQuick Advance Rapid HIV-1/2 Antibody Test, is presently sold only to doctors and clinics. It has already proven to be effective, safe and easy to use. So the remaining hurdles are decisions by the F.D.A. about whether approving such a device is a good idea and whether people can understand the product's label well enough to administer it to themselves.

A 1987 application for an at-home AIDS test kit led to years of controversy. At the time, AIDS advocates and public health officials predicted that such a test would cause widespread suicides, panic and a rush to public health clinics.

At hearings, AIDS advocates handed out copies of an obituary of a San Francisco man who jumped off the Golden Gate Bridge after discovering that he was infected with HIV. An official for the Centers for Disease Control and Prevention told the F.D.A. that such tests could lead to "a

sudden increase in referrals to already overburdened health clinics," according to an F.D.A. document.

Federal regulators stalled the application for nine years, and at-home AIDS testing never caught on.

Some AIDS advocates are now warily supportive of at-home testing.

"For people who don't have access to a clinic or make a decision not to go to a clinic, this is better than nothing," said Gregg Gonsalves of Gay Men's Health Crisis in New York City, which opposed at-home AIDS testing 18 years ago and offers testing and counseling itself. "But it's not a magic bullet."

The switch by advocates is important. Politics have long played a crucial role in many F.D.A. decisions, according to longtime agency observers and previous agency officials. Recently, the agency decided to delay a decision on whether to allow over-the-counter sales of an emergency contraceptive. The decision was seen by some inside and outside of the agency as politically driven, and it led a top agency official to resign in protest.

Dr. Spielberg said that about a quarter of the nearly million people in the [United States](#) who have the HIV virus in their blood do not know that they are infected. And somewhere between 40 percent and 45 percent of those who test positive for HIV do so less than a year before they are diagnosed with AIDS.

Since an HIV infection often takes a decade to develop into full-blown AIDS, "this suggests that people are living with HIV, and spreading HIV for many years before they are aware of their infection," she said.

Many of these people avoid getting tested in clinics for a variety of reasons, including fear of discovery and convenience, studies show. And many hate having to wait more than a week for a lab result, surveys show.

Dr. Spielberg said that she surveyed 240 people infected with HIV and found that more than half said that they would have preferred to have found out about their infection with a rapid at-home test.

Having a rapid, over-the-counter test widely available, Dr. Spielberg said, "is the most powerful strategy we have to bring down HIV infections." People who find out that they are infected with HIV often change their sexual behavior to reduce further infections, she said.

By contrast, OraQuick requires a person to simply swab their gums and then place the swab in a holder. Twenty minutes later, a strip displays one line for a negative result and two lines for a positive one.

The argument against at-home tests has long been that they failed to ensure that patients would get adequate counseling. Activists now acknowledge that many people who get HIV tests in doctors' offices get little or no counseling anyway.

"The counseling that now occurs is very short or abrupt in many settings," said Gene Copello, executive director of The AIDS Institute, a Washington-based policy group.

Doug Michels, president and chief executive of OraSure, said he plans to include advice about counseling on OraQuick's label. "It could be a hotline number, a 24-hour manned counseling center, Web support or printed material that is included in the product," he said.

The company said it would include whatever the advisory committee and the F.D.A. deems is necessary, he said. The company now sells the device for between \$12 and \$17, although the price of an over-the-counter version has yet to be decided, Mr. Michels said.